



INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference IMG/41671PCT1	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/GB 03/04352	International filing date (day/month/year) 08.10.2003	Priority date (day/month/year) 08.10.2002
International Patent Classification (IPC) or both national classification and IPC C08G18/08		
Applicant RANIER LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
 - ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 04.05.2004	Date of completion of this report 17.01.2005
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International application No. **PCT/GB 03/04352**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-28 as originally filed

Claims, Numbers

1-32 as originally filed

Drawings, Sheets

1/8-8/8 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-14, 22, 23, 30-32
	No: Claims	15-21, 24-29
Inventive step (IS)	Yes: Claims	1-14, 22, 23, 30-32
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-32
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Novelty: WO02/11975 (D1) describes a process for making polyurethane by reacting a multifunctional polyisocyanate, a polyol and optionally a chain extender or, alternatively, a prepolymer prepared from these educts. The process described in D1 relates to a highly precise polyurethane manufacturing process ("precision polyurethane manufacture", PPM) in which the product has a predetermined stoichiometry and thermal history. An intimate mixing of the reagents at the molecular level allows the manufacture of tailored linear polyurethanes of narrow molecular weight distribution and narrow polydispersity. In page 9, line 9 to line 14 it is stated that the relative amounts of the two or more reagents and therefore the stoichiometry may be perturbed during the course of the reaction such that the composition of the resultant polymer can be carefully controlled. When the stoichiometric ratio NCO/OH is shifted towards more polyisocyanate, that is to say by increasing the isocyanate index, the hardness of the polyurethane also increases gradually. It follows that a product showing a gradual variation in properties (i.e. hardness) can be manufactured by this process. The apparatus with which this process is carried out is depicted in Fig. 1 of D1: This schematic view is identical with fig. 1 of the present application. Thus, claims 15-17 and 24-29 are considered to be anticipated by D1. D1 however, is silent concerning the reaction of at least two pre-reacted polyurethane streams which are subsequently injected into a mold where the reaction is finalised. Hence the subject matter of claims 1-14 is considered novel over D1.

Claims 18-20 are considered to lack novelty over US 5 545 229 (D2) and US 5 171 281 (D3) which describe a functional biocompatible intervertebral disc spacer made from a central core of an unreinforced elastomeric material and sized so as to approximate the nucleus pulposus of a natural intervertebral disc and an outer ring of a stiffer elastomeric material surrounding said central core(see claim 1). Thus, the device achieves the desired properties by varying the hardness of the elastomeric material in its nucleus and annulus (Article 33, 2 PCT).

Inventive step: A new set of claims based on present independent process claim 1 and to an artificial disc spacer based on present claim 22 could be regarded as involving an

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inventive step (Article 33, 3 PCT).